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Signature		Barbara	nek	ence		
Typed or printed name		Barbara McKenzie		Date	9 Decemb	er 2005

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John M. YANNI

Serial No: 10/539,093 (Conf. #9226)

Filed: 15 June 2005

Examiner:

Group Art Unit:

FOR: TREATMENT OF DRY EYE BY RESTORING 15-LIPOXYGENASE ACTIVITY TO

OCULAR SURFACE CELLS

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. 1.56, 1.97, AND 1.98

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98, Applicants submit the patents, articles, and other information referenced in the specification as filed. The references are listed on the attached PTO Form 1449. Applicants are submitting copies of the foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2), copies of the U.S. patents are <u>not</u> enclosed.

A copy of the International Search Report issued in the PCT application, of which the present application is a 35 U.S.C. §371 application, is also included for the Examiner's convenience.

Applicants request that the listed patents, articles, and other information be considered during prosecution of this application and that they appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

9 New 2005

Date

y: Jenesa Cycl

Teresa/J. Schultz/ Registration No. 40,256

(817) 551-4231

Address for Correspondence: Alcon Research, Ltd. Attn: Teresa J. Schultz

6201 S. Freeway, Mail Code Q-148 Fort Worth, TX 76134-2099 Attorney Docket No.: 2394 US F rk Reduction Act of 1995, no persons are required to res

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known Application Number 10/539,093 Filing Date 15 June 2005 First Named Inventor John M. YANNI Art Unit Examiner Name		
Application Number	10/539,093	
Filing Date	15 June 2005	
First Named Inventor	John M. YANNI	
Art Unit		
Examiner Name		
Attemou Docket Number	2394 LIS F	_

			U. S. PATENT D	OCUMENTS	
Examiner Cite Initials* No.	Cite No.1	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US- 3,991,759	11-16-1976	Urquhart	
	A2	US- 4,131,651	12-26-1978	Shah et al.	
	A3	US- 4,370,325	01-25-1983	Packman	
	A4	^{US-} 4,409,205	10-11-1983	Shively	
	A5	^{US-} 4,744,980	05-17-1988	Holly	
	A6	US- 4,753,945	06-28-1988	Gilbard et al.	
	A7	US- 4,818,537	04-04-1989	Guo	
	A8	US- 4,868,154	09-19-1989	Holly	
	A9	US- 4,914,088	04-03-1990	Glonek et al.	
	A10	US- 4,966,773	10-30-1990	Gressel et al.	
	A11	US- 5,041,434	08-20-1991	Lubkin	
	A12	US- 5,075,104	12-24-1991	Gressel et al.	
	A13	US- 5,174,988	12-29-1992	Mautone et al.	
	A14	US- 5,278,151	01-11-1994	Korb et al.	
	A15		03-01-1994	MacKeen	
	A16	US- 5,294,607	03-15-1994	Glonek et al.	
	A17		12-06-1994	Korb et al.	
	A18	US- 5,403,841	04-04-1995	Lang et al.	
	A19	US- 5,455,265	10-03-1995	Chandraratna	

		FORE	IGN PATENT DOCU	MENTS		
Examinar Cita Foreign Patent Document Publication	Name of Patentee or Pages, Columns, Lines Applicant of Cited Document Where Relevant Passa		6			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

 Complete if Known

 Application Number
 10/539,093

 Filing Date
 15 June 2005

 First Named Inventor
 John M. YANNI

 Art Unit
 Examiner Name

(Use as many sheets as necessary)

Sheet 2 of 5 Attorney Docket Number 2394 US F

Examiner Initials*	Cite No.1	Cite No.1	Cite No.1		Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Nι	ımber-Kind Code ^{2 (il known)}			rigures Appear		
	AA	US-	5,578,586	11-26-1996	Glonek et al.			
	AB	US-	5,620,921	04-25-1997	Sullivan			
	AC	US-	5,620,921 C1	01-09-2001	Sullivan			
	AD	US-	5,696,166	12-09-1997	Yanni et al.			
	AE	US-	5,800,807	09-01-1998	Hu et al.			
	AF	US-	6,204,251	03-20-2001	Cuthbertson			
	AG	US-	4,883,658	11-28-1989	Holly			
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Complete if Known Under the Paperwork Reduction Substitute for form 1449/PTO **Application Number** 10/539,093 INFORMATION DISCLOSURE 15 June 2005 Filing Date STATEMENT BY APPLICANT **First Named Inventor** John M. YANNI Art Unit (Use as many sheets as necessary) **Examiner Name** Attorney Docket Number 2394 US F 5 Sheet 3 of

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	B1	BARABINO S and DANA MR (2004). Animal models of dry eye: a critical assessment of opportunities and limitations. 45(6): 1641-1646	
	B2	BEHRENS et al. (2002). Retroviral gene therapy vectors for prevention of excimer laster-induced corneal haze. IOVS 43(4): 968-977	
	В3	BRASH et al., "Discovery of a second 15S-lipoxygenase in humans", PROC. NATL. ACAD. SCI. USA 94:6148-6152 (1997)	
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	В7	HSI et al., "Evaluation of the activity and localization of 15-Lipoxygenase-1 after introduction into human colorectal carcinoma Caco-2 cells", PROSTAGLANDINS, LEUKOTRIENES AND ESSENTIAL FATTY ACIDS 64 (4 & 5):217-225 (2001)	
	B8	HSI et al., "Opposing Effects of 15-Lipoxygenase-1 and -2 Metabolites on MAPK Signaling in Prostate", THE JOURNAL OF BIOLOGICAL CHEMISTRY 277(43):40549-40556 (2002)	
	B9	International Search Report for PCT/US03/33139 [#2394 WO F]	
	B10	KAMATA et al. (2001). Adenovirus-mediated gene therapy for corneal clouding in mice with mucopolysaccharidosis type VII. MOLECULAR THERAPY 4(4): 307-312	

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	- -	NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Examiner Initials*	Cite No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	LEMP, "Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes", The CLAO Journal, 21(4):221-232 (1995)	
	C2	LIMINGA et al (1994). Arachidonate 15-lipoxygenase in human corneal epithelium and 12- and 15-lipoxygenases in bovine corneal epithelium: comparison with other bovine 12-lipoxygenases. Biochim Biophys Acta. 1210(3): 288-296	
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	C4	MAROM et al., "Human Airway Monohydroxyeicosatetraenoic Acid Generation and Mucus Release", JOURNAL OF CLINICAL INVESTIGATION 72:122-127 (1983)	
	C5	MARTIN et al. (2002). Gene delivery to the eye using adeno-associated viral vectors, METHODS 28 267-275	
	C6	MCCULLEY and SHINE, "Tear Film Structure and Dry Eye", Contactologia, 20(4):145-49 (1998)	
	C7	NAKMURA et. al., "Gefarnate Stimulates Secretion of Mucin-Like Glycoproteins by Corneal Epithelium in Vitro and Protects Corneal Epithelium from Desiccation in Vivo", EXPERIMENTAL EYE RESEARCH 65:569-574 (1997)	_
	C8	PETERSON CM et al. (2002). Dry eye syndrome in postmenopausal women. JAMA 287(5): 585-586	
	C9	PFEIFER A and VERMA IM (2001). Gene Therapy: promises and problems. Annu Rev Genomics Hum Genet. 2: 177-211	
	C10	SHAPPELL et al., "15-Liposygenase-2 (15-LOX-2) Is Expressed in Benign Prostatic Epithelium and Reduced in Prostate Adenocarcinoma", AMER. J. PATH. 155(1):235-245 (1999)	

Examiner	Date Considered	
Signature	Considered	

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				Art Unit	·	
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Sheet	5	of	5	Attorney Docket Number	2394 US F	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	D1	SHAPPELL et al., "15-Lipoxgenase-2 Expression in Benign and Neoplastic Sebaceous Glands and Other Cutaneous Adnexa", J. INVESTIGATIVE DERMATOLOGY. 117(1):36-43 (2001)	
	D2	SHINE and MCCULLEY, "Keratoconjunctivitis Sicca Associated With Meibomian Secretion Polar Lipid Abnormality", ARCHIVES OF OPHTHALMOLOGY 116(7):849-52 (1998)	
	D3	STECHSCHULTE et al., "Rapid Ocular Angiogenic Control via Naked DNA Delivery to Cornea", INVEST. OPHTHALMOL. VIS. SCI. 42(9):1975-1979 (2001)	
	D4	VERMA, I. M. and SOMIA, N. (1997). Gene therapy-promises, problems and prospects. NATURE 389: 239-242	
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Examiner	Date	
Signature	Considered	

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